Morpheus

APR 0 3 2014

K133937
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510(k) Summary
Prepared November 6, 2013
(Revised: March 14, 2014)

Sponsor: Morpheus Imaging, Inc

Contact Person: John Axerio-Cilies Ph.D.

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Submission Date: November 6, 2013

Device Name: HeartScan Software

Common Name: Radiology Imaging Software

Classification:
Regulatory Class: II
Review Category: 21 CFR 892.2050 (LLZ)
Classification Panel: Radiology

A. Legally Marketed Predicate Devices

The Morpheus HeartScan software device is substantially equivalent to the MedVoxel Systems Inc. MedVoxel HeartPro Software System (K103565).

B. Device Description:

Morpheus HeartScan is a web-accessible image analysis software application. The application is intended to visualize and quantify cardiac-specific MRI data in DICOM format. HeartScan has features for loading, saving, generating screen displays, and aggregating flow statistics.

Pre-existing MR images are uploaded via the web to the HeartScan software application where image corrections (specific to aliasing errors) are applied to the set of images prescribed by the user. Automatic or manual vessel segmentation is performed and advanced analysis algorithms are applied to quantify blood flow. The images and blood flow can be simultaneously visualized at any plane using multi-planar reconstruction (MPR) with color flow fusion. Reproducible test results are produced and stored in the image study.

HeartScan does not interface directly with any MR or data collection equipment, instead HeartScan imports data files previously generated by such equipment. The software application applied advanced automated methods to avoid tedious, time-consuming manual methods. The software does not perform any functions which cannot be accomplished by a trained user utilizing manual tracing methods; the purpose of the software is to save time and automate potential error-prone manual tasks.

C. Intended Use

HeartScan consists of software that analyzes DICOM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. HeartScan specifically analyzes the blood flow to the heart and its major vessels using multi-slice, multi-phase and velocity encoded MR images. It provides clinically relevant and reproducible, quantitative data and has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners. The data produced by HeartScan is intended to be used to support qualified cardiologist, radiologist or other licensed professional healthcare practitioners for clinical decision making. It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.

D. Substantial Equivalence

The submission device is substantially equivalent to MedVoxel Systems Inc. MedVoxel HeartPro Software Application (K103565) as described in the table below:

Table 1 Comparison Table

Feature/Specification	Predicate Device MedVoxel HeartPro Software Application K103565	Subject Device Morpheus HeartScan Software
Indication for use	HeartPro consists of software that analyzes DICOM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. HeartPro specifically analyzes the blood flow to the heart and its major vessels using multi-slice, multi-phase and velocity encoded MR images. It provides clinically relevant and reproducible, quantitative data and has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners. The data produced by HeartPro is intended to be used to support qualified cardiologist, radiologist or other licensed professional health care practitioners for clinical decision making. It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.	HeartScan consists of software that analyzes DICOM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. HeartScan specifically analyzes the blood flow to the heart and its major vessels using multi-slice, multi-phase and velocity encoded MR images. It provides clinically relevant and reproducible, quantitative data and has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners. The data produced by HeartScan is intended to be used to support qualified cardiologist, radiologist or other licensed professional health care practitioners for clinical decision making. It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.
Intended Users	qualified cardiologist, radiologist or other licensed professional health care practitioners	qualified cardiologist, radiologist or other licensed professional health care practitioners
Class	II	II

Morpheus

Feature/Specification	Predicate Device MedVoxel HeartPro Software Application K103565	Subject Device Morpheus HeartScan Software
Regulation Code	21CFR 892.2050 LLZ	21CFR 892.2050 LLZ
Data Acquisition		
Workstation operating system	Yes	Yes
Images from all MRI scanners supported	Yes both 1.5T and 3.0 T	Yes both 1.5T and 3.0 T
Image input	Supports DICIOM 3.0	Supports DICOM 3.0
Data acquisition protocol for blood flow analysis	Cardiovascular images: multi-phase, multi-slice and velocity encoded images acquired from MRI scanners	Cardiovascular images: multi-phase, multi-slice and velocity encoded images acquired from MRI scanners
Workflow		
User Interactions	User can browse, select and load CMRI scan files; save and load analyses; export to files; generate reports with quantitative data; display DICOM information	User can browse, select and load CMRI scan files; save and load analyses; export to files; generate reports with quantitative data; display DICOM information
Image manipulation	Pan/zoom; magnify; maximize and minimize; adjust window level, contrast, brightness; single image ROI placement; automated 2D ROI copy/edit functions; 2D velocity color map.	Pan/zoom; magnify; maximize and minimize; scroll through slice stack; adjust window level, contrast, brightness; single image ROI placement; automated 2D ROI copy/edit functions; 2D velocity color map.
ROI vessel contour detection and editing	Automatic contour detection with user input; can be changed manually	Automatic contour detection with user input; can be changed manually
Data Analysis		
2D measurements	ROI tools and statistics	ROI tools and statistics
Quantitative assessment of cardiac function	Measurement algorithm generates clinical data, including parameters such as net blood flow rate, and net blood flow volume.	Measurement algorithm generates clinical data, including parameters such as net blood flow rate, and net blood flow volume.
Phase Aliasing Error Correction	Phase alias error correction provided via user interface	No
Eddy Current Correction (ECC)	Yes	Yes
Data Output		
Dynamic display of ventricular contractions	Yes	Yes
Comparative review	2D	2D
Measurement Information	Blood flow chart displayed; Net blood flow rate; Net blood flow volume	Blood flow chart displayed; Net blood flow rate; Net blood flow volume

E. Performance Data

Nonclinical verification and validation test results established that the device meets its design requirements and intended use, that it is as safe, as effective, and performs as well as the predicate device, and that no new issues of safety and effectiveness were raised. The HeartScan software was designed, verified, and validated according to the company's Design Control process and has been subjected to extensive safety and performance testing as shown in the test results provided in this submission. Verification and validation testing data demonstrate that the device meets all of its specifications including compliance with the following standards:

- Digital Imaging and Communications in Medicine (DICOM); PS 3.1 - 3.20 (2011)
- Medical device software – Software Life Cycle Process, IEC 62304
- Medical devices - Application of risk management to medical devices, 14971 Second edition 2007-03-01
- Medical Devices - Application of Usability Engineering to Medical Devices, ISO 62366

Nonclinical verification and validation test results establish that the device generates reproducible data. Specific test cases were created during verification that included multiple analysis of the same ROI within the same dataset to confirm that the device generated the same output within an acceptable criterion. Additionally, validation between HeartScan and the predicate device included analyzing the same datasets and ROI to confirm that HeartScan outputs were within a clinically acceptable range compared to that of the predicate. Results conclude that HeartScan is capable of generating clinically acceptable reproducible data in comparison with a similar currently marketed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 3, 2014

Morpheus Imaging, Inc.
% John Axerio-Cilies, Ph.D.
CEO
1700 4th Street MC 2522 Byers Hall 214
SAN FRANCISCO CA 95158-2330

Re: K133937
Trade/Device Name: HeartScan Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 14, 2014
Received: March 25, 2014

Dear Dr. Axerio-Cilies:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133937

Device Name
Morpheus HeartScan

Indications for Use *(Describe)*
HeartScan consists of software that analyzes DICOM-compliant cardiovascular images acquired from magnetic resonance (MR) scanners. HeartScan specifically analyzes the blood flow to the heart and its major vessels using multi-slice, multi-phase and velocity encoded MR images. It provides clinically relevant and reproducible, quantitative data and has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners. The data produced by HeartScan is intended to be used to support qualified cardiologist, radiologist or other licensed professional healthcare practitioners for clinical decision making. It is a support tool that provides relevant clinical data as a resource to the clinician and is not intended to be a source of medical advice or to determine or recommend a course of action or treatment for a patient.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*